

Remarks/Arguments:

Claims 15 and 29, currently amended, and claims 16-24 and 26-28, previously presented, are pending.

Claims 1-14 and 25 are canceled, without prejudice or disclaimer.

Claim 17 was implicitly found allowable over the prior art by the PTO. That is, claim 17 is neither listed among the rejected claims, nor discussed, in any of the prior art rejections.

Applicants wish to thank the examiner for expressly setting forth (in the instant Office Action) the withdrawn objections and rejections, previously of record. Applicants also wish to thank the examiner for indicating the clerical error in claim 29 (discussed below) and, thereby, providing for a timely correction of the error.

The objection to claim 29 is overcome by present claim 29. In accordance with the foregoing amendments to the claims, "int hat" is changed to "in that" in claim 29. Withdrawal of the objection appears to be in order.

Claims 15 and 17 were rejected under 35 USC 112, second paragraph, as allegedly being indefinite. Reconsideration is requested in view of the changes to the rejected claims effected hereby, taken in conjunction with the following remarks.

With respect to claim 15, the §112, ¶2, rejection appears to be the result of the word "identifying" being misinterpreted. In the present claims, "identifying" means the same as *determining* or *detecting*. For example, the present specification (page 5, lines 16-18) teaches (emphasis added)

the method according to the invention is to be considered an enzymatic reporter assay which detects the effect of substances on bacterial factors.

In other words, in accordance with the presently claimed method, "a possible active substance" is assayed to *detect* whether it is, in fact, an active substance. By way of explanation, for example, the present claims do not require that the "possible active substance" be unknown: a known substance—already characterized structurally and compositionally—can be used as the "possible active substance" in the presently claimed method.

The present claims, therefore, do not use the word "identifying" to mean the same as *naming* or *characterizing* (by structure or composition), which is the interpretation apparently given by the PTO in the context of the §112, ¶2, rejection.

Therefore, Applicants respectfully submit that claim 15 is not indefinite, as alleged in the rejection under §112, ¶2. Nevertheless, in a good-faith effort to advance prosecution, Applicants have hereby amended the pending claims by changing "identifying" to "detecting"—and "identify" to "detect"—as used in the present specification (explained above).

With respect to claim 17, the claim is not indefinite. According to the statement of rejection, claim 17 is indefinite because the limitation "the bacteria cell wall" allegedly lacks antecedent basis.

With all due respect, the lack of express antecedent basis for "the bacteria cell wall" (emphasis added) does not render the claim indefinite under §112, ¶2. According to MPEP 2173.05(e) "Antecedent Basis":

Inherent components of elements recited have antecedent basis in the recitation of the components themselves. For example, the limitation "the outer surface of said

sphere" would not require an antecedent recitation that the sphere has an outer surface.

Just as reciting "the outer surface of said sphere" does not require antecedently reciting that the sphere "has an outer surface" (i.e., antecedently reciting "sphere" is sufficient), it is not necessary to antecedently recite that the bacteria "has a cell wall" (merely reciting "a bacteria" is sufficient). MPEP 2173.05(e). Accordingly, the rejection of claim 17 under §112, ¶2, is overcome.

For the foregoing reasons, the rejection of claims 15 and 17 under §112, ¶2, is overcome. Withdrawal of the rejection appears to be in order.

Claims 15-16, 20, 24, 26 and 29 were rejected under 35 USC 102(b) as allegedly being anticipated by Samuelson (*J. Bact.*, 1995, vol. 177(6): 1470-1476). Reconsideration is requested.

For anticipation under § 102 to exist, each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985). The "absence" from a prior art reference of a single claim limitation "negates anticipation." *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81, 84 (Fed. Cir. 1986). A reference that discloses "substantially the same invention" is not an anticipation. *Jamesbury Corp.* To anticipate the claim, each claim limitation must "*identically* appear" in the reference disclosure. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) (*emphasis added*).

When the PTO

asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears in the reference.

In re Rijckaert, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). An argument by the PTO is "not prior art."
28 USPQ2d at 1957.

The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because *it may doubt* that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis.

In re Warner, 154 USPQ 173, 178 (CCPA 1967) (*emphasis in original*).

Samuelson does not teach (or even suggest) all limitations on the rejected claims, allegations to the contrary in the statement of rejection, notwithstanding. At a minimum, Samuelson fails to meet the limitation to

at least one reporter substance having a different enzymatic activity when not covalently bonded to the surface of the Gram-positive bacteria from that exhibited when it is covalently bonded to the surface of the Gram-positive bacteria.

This "reporter substance"—as expressly defined in the rejected (and present) claims—is apparently absent from Samuelson.

Note is taken that the statement of rejection (Office Action, page 6) alleges:

There is a charged repetitive region postulated to interact with the peptidoglycan cell wall and a region common for Gram-positive cell surface bound receptors containing an LPXTGX motif, a C-terminal hydrophobic region and a charged tail (page 1475).

And, present claim 21 limits the (generic) "reporter sequence," recited in rejected claim 15, to a sub-generic)

hybrid polypeptide [that] has a succession of the following sequence segments: N-terminal signal peptide, enzyme, sequence segment having the sequence LPXTG (SEQ ID NO: 11), hydrophobic sequence segment, and charged sequence segment.

The obvious similarities between the PTO argument (quoted above), on the one hand, with the "reporter sequence" sub-genus recited in claim 21, on the other, indicates that the PTO alleges: by describing (allegedly) the "reporter sequence" sub-genus recited in claim 21, Samuelson (page 1475) meets the "reporter sequence" genus recited in the rejected claims. However, the PTO, itself, admits that Samuelson neither (1) describes the subject matter of claim 21 nor (2) meets the "reporter sequence" limitation on the claims rejected under §102(b).

First, the PTO implicitly admits that Samuelson (alone) fails to describes the subject matter of claim 21, because the PTO does not allege that claim 21 is anticipated; i.e., claim 21 is not one of the claims rejected under §102(b).

Secondly, the PTO admits that Samuelson (alone) fails to meet the "reporter sequence" limitation by stating (Office Action, page 8) "Samuelson et al.. . . do not teach the . . . hybrids polypeptide succession." That is, the "hybrids polypeptide succession" constitutes the

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(Office Action, page 6, referenced above) allegedly meeting the "reporter sequence".limitation on the claims rejected under §102(b). Since the PTO admits "Samuelson et al.. . . do not teach the . . . hybrids polypeptide succession," the PTO acknowledges that at least one limitation on the rejected claims is *absent* from Samuelson and, accordingly, the PTO admits that anticipation of the rejected claims is *negated*. *Kolster Speedsteel A B*, 230 USPQ at 84.

Besides the failure of Samuelson to meet the "reporter substance" limitation, Samuelson fails to teach, and the statement of rejection fails to explain where and how the reference describes, steps b)" and "d)" recited in rejected claim 15, i.e., the steps "b) contacting the sample with a possible active substance" and "d) correlating the enzymatic activity of the reporter substance to a capability of the [possible] active substance to affect the covalent bonding of polypeptides to the surface of Gram-positive bacteria."

First, the failure of the PTO to explain where and how the claim limitations are met renders the rejection improper. When the PTO

asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears in the reference.

Rijckaert, 28 USPQ2d at 1955, 1957 (Fed. Cir. 1993). An argument by the PTO is "not prior art." 28 USPQ2d at 1957.

Secondly, simply put, Samuelson fails to teach (or even suggest) a method (as presently claimed) that compares (1) the capability of a substance to affect the covalent bonding of polypeptides to the surface of Gram-positive bacteria with (2) the enzymatic activity of a "reporter substance" that has different enzymatic effects depending on whether or not it is covalently bonded to the surface of Gram-positive bacteria.

Accordingly, the "absence" from Samuelson of at least one limitation on the rejected claims "negates anticipation" of rejected claims by Samuelson. *Kolster Speedsteel AB*, 230 USPQ at 84. Since each limitation on the rejected claims does not "identically appear" in the Samuelson disclosure, the reference fails to anticipate the rejected claims. *Gechter*, 43 USPQ2d at 1032.

Additionally, Applicants do note that Samuelson (page 1473, right-hand column) does teach that albumin-binding protein (ABP) serves as a reporter. However, the "reporter substance" recited in the present claims is totally different.

The ABP reporter of Samuelson does not meet the "enzymatic reporter" limitation on the present claims. That is, Samuelson does not teach, or even suggest, use of an enzymatic reporter molecule having an enzymatic activity which differs depending on whether or not it is covalently bonded to the cell surface, which—besides being a limitation on the rejected claims— is an underlying concept of the presently claimed invention. Contrary to the laborious multi-step principle of Samuelson, requiring a washing/fractionating step, the presently claimed invention provides a uniquely elegant assay principle: by using a reporter molecule having an enzymatic activity that differs depending whether or not it is covalently bonded to the cell surface, the presently claimed invention avoids the need of such additional washing/fractionating step. This is a great advantage of the presently claimed invention, especially if one wishes to analyze a multitude of possibly active substances and detect those that affect the covalent bonding of polypeptides to the surface of Gram-positive bacteria (as it is the case for the present invention).

For the foregoing reasons, the rejection of claims 15, 16, 20, 24, 26 and 29 under §102(b) as being allegedly anticipated by Samuelson is overcome. Withdrawal of the rejection appears to be in order.

Claims 18-19, 21, and 27-28 were rejected under 35 USC 103(a) as being unpatentable over Samuelson in view of Schneewind (*Science*, 1995, vol. 268:103-105). Reconsideration is requested.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art," *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970), "and it is error to ignore specific limitations distinguishing over the [prior art] reference." *Ex parte Murphy*, 217 USPQ 479, 481 (PO Bd. App. 1982). A "ground of rejection is simply inadequate on its face . . . [when] the cited references do not support each limitation of [the] claim." *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002).

The rejection under §103(a) based on combining the teachings of Samuelson with those of Schneewind fails for the same reason set forth above with respect to the §102(b) rejection. That is, the present §103(a) rejection relies on the same teachings of Samuelson relied on in the §102(b) rejection; and, since the reliance on Samuelson in the §102(b) rejection is misplaced (as explained above), reliance on Samuelson in the §103(a) rejection is likewise misplaced in the §103(a) rejection and, so, renders the rejection fatally flawed.

The aforementioned fatal deficiency in Samuelson, i.e., failing to support the "reporter molecule" limitation, is neither taught nor suggested by combining Samuelson with Schneewind. Schneewind teaches to elucidate the structure of the cell wall anchor of surface proteins in *Staphylococcus aureus*. Schneewind does not even teach a method for detecting active substances, let alone the use—as in the present claims—of an enzymatic reporter molecule having an enzymatic activity that differs depending on whether or not it is covalently bonded to the cell surface.

Accordingly, the combined teachings of Samuelson and Schneewind fails to support all limitations on the rejected claims, as required to establish a *prima facie* case of obviousness. *Royka, supra*. And, since "the cited references do not support each limitation of [each rejected] claim," the rejection is "inadequate on its face." *Thrift*, 63 USPQ2d at 2008.

For the foregoing reasons, the rejection of 18, 19, 21, 27 and 28 under §103(a) as being allegedly unpatentable over Samuelson in view of Schneewind is overcome. Withdrawal of the rejection appears to be in order.

Claims 22 and 23 were rejected under 35 USC 103(a) as allegedly being unpatentable over Samuelson in view of Schneewind and further in view of Strauss et al. (*Mol. Microbio.*, 1996, vol. 21(3):491-500). Reconsideration is requested.

First of all, the rejection of claims 22 and 23 under §103(a) cannot be maintained for the same reasons set forth above with respect to the rejection under §103(a) of claims 18, 19, 21, 27 and 28. In the rejection of claims 22 and 23, Samuelson and Schneewind were relied on the same reasons as in other §103(a) rejection; and, therefore, since the combined teachings of Samuelson and Schneewind cannot support the previous rejection under §103(a), they, likewise, fail to support the rejection of claims 22 and 23 under §103(a). And, since Strauss provides neither teaching nor suggestion that makes up for the fatal deficiency in the combined teachings of Samuelson and Schneewind, the rejection of claims 22 and 23 is "inadequate on its face," *Thrift*, 63 USPQ2d at 2008, for the same reasons set forth above.

Secondly, Strauss has a different focus than that of the present, rejected claims, i.e., Strauss focuses on a surface display technique. Furthermore, one skilled in the art would have arrived at, neither, the feature of the presently claimed invention, nor, its underlying concept, of using an enzymatic reporter molecule having an enzymatic activity that differs depending on whether or not it is covalently bonded to the cell surface, let alone to use such a concept for the purpose of detecting possibly active substances that affect the covalent bonding of polypeptides to the surface of Gram-positive bacteria.

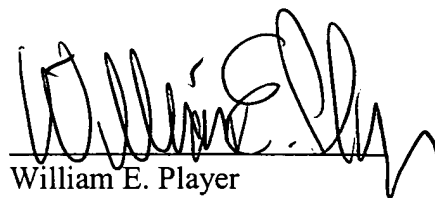
Accordingly, for the foregoing reasons, the rejection of claims 22 and 23 under 35 USC 103(a) based on the combined teachings of Samuelson, Schneewind and Strauss is overcome. Withdrawal of the rejection appears to be in order.

Favorable action is requested.

Respectfully submitted,

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